

Remarks

Response to Outstanding Office Action

This response to office action and request for continued examination is being filed after the six month statutory period for reply. The entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional. If required, reinstatement of the case is respectfully requested.

Status of the Claims

Claims 1-16 are pending in the application. All claims stand rejected. By this paper, independent claim 1 and 9 have been amended, claims 6 and 7 have been cancelled and new independent claim 16 has been added. For the reasons set forth below, applicant submits that each of the pending claims is patentably distinct from the cited prior art and in condition for allowance. Reconsideration of the claims is therefore respectfully requested.

Claim Rejections – 35 U.S.C. §§ 112 first paragraph

Claims 1, 6, 7 and 9 stand rejected under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement. In particular, the examiner specifies the following language of the claim, “a larger extent of the second surface is associated with the tapered protrusion on the second surface.”

Applicant points to the language in support of the claim amendment which can be found on page 10, lines 20-28:

...the closure 130 is provided with three slits which are referred to by reference numerals 162 in the embodiment of Fig. 7 and the reference numeral 164 in the embodiment of Fig. 8. The slits 162, 164 extend radially outwardly from a first, common point of contact 166 provided at first surface 156 of closure member 130...In the embodiment of Fig. 8, the slits 164, however, have a length at the second surface 160 which is close to zero, i.e. the three slits 164 meet in a single, second point of contact 168.”

Applicant also points to the language in support of the claim language which can be found on page 2, lines 15-25:

...the closure comprising a closure member which is made from a resilient material and which defines a first and second end surface...and at least one passage slit, the passage slit being arranged to open by a tubular member being extended therethrough, the passage slit having a length at the first surface which is longer than its length on the second surface, i.e. the passage slit having a wider extent at the first surface than at the second surface. In other words, at one surface of the closure member, the transverse length of the slit is shorter than the transverse length of the slit at the other surface of the closure member.

Claim Rejections – 35 U.S.C. §§ 112 second paragraph

Claims 1, 6, 7 and 9 stand rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 9 have been

amended to overcome the examiner's rejection. Claims 6 and 7 have been cancelled to obviate the rejection with respect to claims 6 and 7.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-15 stand rejected under 35 U.S.C. § 103(a) as obvious by, U.S. Patent No. 5,199,948 to McPhee ("McPhee") in view of U.S. Patent No. 5,149,327 to Oshiyama ("Oshiyama"), and further in view of U.S. Patent No. 5,114,408 to Fleischhaker, *et al.* ("Fleischhaker"). Applicant has amended independent claim 1 to clarify the differences between the claimed invention and the cited references.

Amended Independent Claim 1

Claim 1 has been amended to recite, "...closure member is tapered along the entire length of the tapered core section which is positioned in the longitudinal passage of the connector." On Page 4, lines 7-9 of the specification it explains, "The closure member may define a core section which fits into a longitudinal passage in the connector... The core section may be tapered, so that its diameter is larger at its proximal end than at its distal end."

Claim 1 has been further amended to recite, "larger extent of the ~~second~~ passage slit is associated with the tapered core section ~~protrusion~~ on the ~~second~~ first surface of the ~~core section~~ closure member such that when a tubular member extends through the passage slit the tubular member will not stretch or deform the closure member." On page 2, lines 31-24 and Page 3, lines 1-2 it explains, "by providing a slit as explained above, the risk of improper alignment of the catheter or

stent system and the closure is reduced and thereby also the risk of the catheter or stent system stretching/deforming the closure to such an extent in the area of the slit that a gap is created between an outer wall of the catheter or stent system and the closure”

Applicants respectfully submit that claim 1 as amended distinguishes over the teachings of McPhee, Oshiyama, Fleishchaker. In particular, these cited references do not teach, “passage slit having a larger extent at the ~~first~~ second surface than the ~~second~~ first surface such that the smaller extent of the passage slit is positioned in the concave portion at the ~~first~~ second surface and a larger extent of the ~~second~~ passage slit is associated with the tapered core section ~~protrusion~~ on the ~~second~~ first surface of the ~~core section~~ closure member such that when a tubular member extends through the passage slit the tubular member will not stretch or deform the closure member.”

Additionally, the cited references do not teach that, “[the] closure member is tapered along the entire length of the tapered core section which is positioned in the longitudinal passage of the connector.”

In particular, McPhee teaches a septum 15 having T-shaped cross-section which terminates in a tapered tip 31 at one end. See Column 3, lines 41-44. Most of the length of the T-shaped cross-section which extends into the lumen formed by cylindrical wall 24 is not tapered, but is instead straight. See Figure 1. Additionally, this portion of the T-shaped cross-section is positioned in contact with ribs 25 positioned along the inside diameter of cylindrical wall 24. See Column 4, lines 7-13, See also Figure 1. This teaches away from the teaching of claim 1 which recites that,

“closure member is tapered along the entire length of the tapered core section which is positioned in the longitudinal passage of the connector so that its diameter is larger at its proximal extent than at its distal extent and such that the walls of the tapered core section do not contact the walls of the longitudinal passage of the connector when the closure member is not engaged by the tubular member ... such that when a tubular member extends through the passage slit the tubular member will not stretch or deform the closure member.”

Oshiyama also fails to teach a closure for a valve having a protrusion of the second surface of the core section which is tapered so that its diameter is larger at its proximal extent than at its distal extent and where the walls of the protrusion do not contact the walls of the longitudinal passage of the connector when the closure member is not engaged by a tubular member. Additionally Oshiyama fails to disclose or suggest a passage slit having a larger extent at the first surface than the second surface where the smaller extent of the passage slit is positioned in the concave portion at the first surface and a larger extent of the second surface is associated with the tapered protrusion on the second surface of the core section.

Fleishchhaker teaches a hemostasis valve having a relatively small opening in the sealing neck and a slit concave exit base. However, the teaching of Fleishchhaker does not realize the benefits of the design of the present invention. As a result, the reversal of the components of Fleishachheker is not merely a matter of design choice that would be anticipated by one skilled in the art but changes the operability and effectiveness of the disclosed valve design. The design of Fleishchhaker fails to disclose, “the closure member is made from a resilient material

which is adapted to deform in the area of said protrusion and said indentation when said face and said end surface are biased **towards** each other.” Emphasis added.

Additionally, Fleishchhaker teaches away from the design of the present invention, “By virtue of the concave nature of the exit face (4) and the fact that the edges of the exit face are in contact with the walls of the valve housing, there is added pressure to maintain the slit valve in the closed position” See Fleishchhaker col. 4, lines 53-57. In fact, Fleishchhaker teaches, “the slit (14) is contained in the concave exit face (4) which preferably is maintained in contact with the walls of the valve housing (3).” The design of Fleishchhaker is contrary to the amended claims. Claim 1 as amended recites, “closure member is tapered along the entire length of the tapered core section which is positioned in the longitudinal passage of the connector so that its diameter is larger at its proximal extent than at its distal extent and such that the walls of the tapered core section do not contact the walls of the longitudinal passage of the connector when the closure member is not engaged by the tubular member.”

Additionally, there is no teaching, suggestion or motivation to combine the teachings of McPhee, Oshiyama, Fleishchhaker. The T-shaped septum 15 disclosed by McPhee, discloses only a typical slit 33, which does not have the, “a larger extent at the ~~first~~ second surface than the ~~second~~ first surface such that the smaller extent of the passage slit is positioned in the concave portion at the ~~first~~ second surface and a larger extent of the ~~second~~ passage slit is associated with the tapered core section ~~protrusion~~ on the ~~second~~ first surface of the ~~core section~~ closure member such that when a tubular member extends through the passage slit the tubular member will not

stretch or deform the closure member” as recited by the present invention. In point of fact, the claimed invention is directed to solve, “stretch[ing] or deform[ing] [of] the closure member,” which tend to result from valve designs which contact the lumen wall such as disclosed in McPhee. See page 2, lines 31-24 and Page 3, lines 1-2.

Similarly, the slit of Oshiyama is utilized with a disk shaped valve member which can also tend to stretch or deform in a manner that affects the integrity and proper operation of the seal. In point of fact, the claimed invention is directed to solve, “stretch[ing] or deform[ing] [of] the closure member,” which can result from valve designs such as those disclosed in Oshiyama. See page 2, lines 31-24 and Page 3, lines 1-2. There is no teaching, suggestion or motivation by Oshiyama of the use of the disclosed slits with other than the single valve member which comprises disk shaped valved member disclosed in Oshiyama.

Because McPhee, Oshiyama and Fleishchaker fail to teach or suggest a closure for a valve having the advantages and structure of the claimed invention, claim 1 and the dependent claims depending therefrom, claims 1-15 should be in condition for allowance.

New Independent Claim 16

New claim 16 has been added. Claim 16 includes many of the limitations of amended claim 1. However, claim 16 recites that:

...the passage slit having a larger extent at the first surface than the second surface such that the smaller extent of the passage slit is positioned in the tapered core section at the first surface and a larger extent of the passage slit

is associated with the concave portion at the first surface thereby defining a guide for the catheter to at least partially force the tubular member being introduced through the closure member into a particular angular alignment with respect to the closure member. See page 2, lines 18-27.

McPhee, Oshiyama and Fleishchhaker fail to teach or suggest a closure for a valve having the advantages and structure of the claimed invention, claim 16 including the larger extent of the passage slit being associated with the concave portion and the smaller portion of the passage slit being associated with the tapered core section. As such, applicant respectfully suggests that claim 16 is in condition for allowance.

Conclusion

For at least the foregoing reasons, the cited prior art references, whether considered individually or in combination, fail to disclose each of the limitations in any of the pending independent claims. For at least the same reasons, each of the claims depending therefrom are also patentably distinct from the cited prior art.

In view of the foregoing, all pending claims represent patentable subject matter. A Notice of Allowance is respectfully requested.

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